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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,777	12/29/2000	Hiroyuki Morimoto	2500.6	3913
5514	7590	09/13/2004	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER

1615

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/647,777	<b>Applicant(s)</b> MORIMOTO ET AL.	
	<b>Examiner</b> Susan T. Tran	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.  
2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 42-70 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 42-70 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment filed 06/07/04.

#### ***Response to Amendment***

The amendment filed 06/07/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "molding material not containing a lubricant"; "without destroying said granule bearing a coating film"; "without destroying the granule"; lubricant "essentially only on a surface"; and "[m]ethod for enhancing function of a compressed tablet". In accordance with MPEP § 7.14.02, applicant should specifically point out support for any amendment made to the disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitations:

- 1) "molding material not containing a lubricant";
- 2) "without destroying said granule bearing a coating film";
- 3) "without destroying the granule";
- 4) lubricant "essentially only on a surface"; and
- 5) "[m]ethod for enhancing function of a compressed tablet".

### ***Specification***

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment ***must be accompanied by an affidavit or declaration*** executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Applicant's attention is called to the citation of the Japanese applications/patents JP-A-71-24231, JP-A-62-103012, JP-A-57-150612, and JP-A2-106 throughout the specification.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al. EP 0 650 826 A1, in view of Roche US 5,075,114.

Morimoto teaches a tablet compressing method using tableting machine with lubricant spraying mean (see abstract). The method comprising spraying lubricant uniformly on the surface of an upper punch, a lower punch, and a die, filling the die with pharmaceutical materials, and compressing the pharmaceutical material to form a drug tablet (columns 2-3 and columns 5-7).

Morimoto does not teach the specific form of pharmaceutical material being claimed, such as, coated granule or granule in a matrix base. Nonetheless, Morimoto teaches that his tableting method can be used for tableting many kinds of tablets such as powdered or granular medicine, and so on (column 7, lines 34-38).

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tableting machine having die wall and punches (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the pharmaceutical materials to be tabletted in Morimoto using the coated drug

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granule in view of the teaching of Roche, because the references teach the use of compressed tableting machine to compress pharmaceutical materials.

Claims 42-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsushima et al. US 6,036,974, in view of Roche US 5,075,114.

Tsushima teaches a method for preparation of tablet comprises preparing the tableting material containing medicines and excipients, coating on the surface of the tableting material a lubricant, coating the surface of the punches with lubricant, filling the die with the coated tableting material, and compressing to obtain tablet (columns 2 and 6).

Tsushima does not teach the specific form of pharmaceutical material being claimed, such as, coated granule in a matrix base.

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tableting machine having die wall and punches (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the tableting materials of Tsushima using the coated drug granule in view of the teaching of Roche, because the references teach the use of compressed tableting machine to compress pharmaceutical materials.

It is noted that the reference is silent as to the teaching of the percent amount of lubricant being coated onto the surface of the die and punches. However, generally, differences in concentration will not support the patentability of subject matter

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encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable amount of lubricant to obtain a smooth surface tablet. As well as the dividing line on the tablet, it would have been obvious for one of ordinary skill in the art, because dividing line, groove line, marking line, or scored tablet is well known in pharmaceutical art. Moreover, absent of evident on the contrary, the burden is shifted to applicant to provide data showing the amount of surfactant uses by the cited references do not fall within the claimed range.

### ***Response to Arguments***

Applicant's arguments filed 06/07/04 have been fully considered but they are not persuasive.

Applicant argues that Morimoto does not disclose selecting active substance-containing granules which are coated with film, or granule comprising active substance in a base matrix. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Morimoto is cited in combination with Roche.

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Applicant argues that Tsushima does not teach that lubricant cannot be in the paste. However, no data has been provided showing a side-by-side comparison of the unexpected result without the present of surfactant in the paste. Accordingly, the burden is shifted to applicant to establish that the present of minute amount of surfactant in the paste would place a detrimental effect upon the desirability of forming a compressed tablet.

Applicant argues that the combination of references still fail to teach or suggest limiting the amount of lubricant to less than 0.2%. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Moreover, absent of evident on the contrary, the burden is shifted to applicant to provide data showing the amount of surfactant uses by the cited references do not fall within the claimed range. Applicant's attention is directed to column 6, lines 34-42, Morimoto teaches pulsating air generator is used to suck extra lubricant, therefore, prevent large amount of lubricant deposits on the surface of the turn table unnecessarily, and suitable amount of lubricant is used.

Applicant incorporates table 2 from page 50 of the specification to show unexpected result achieved by the present invention. Table 2 shows tableting pressure, tableting hardness, and disintegration time. However, it is noted that none of the limitations in table 2 are recited in the claims. furthermore, it is also noted that the amount of lubricant used in both, comparisons 1 and 2 are within the claimed range,

e.g., 0.03% (see specification pages 48 and 49. Accordingly, the evidence submitted is insufficient to establish unexpected results over the cited references.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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